



Coordinating medical writing and publishing in the pharmaceutical industry

An Interview with Christoph Pfannmüller

Tell us something about your background and how you came to be a Medical Writing Coordinator at Merck in Darmstadt, Germany.

I am a nutritional scientist by training and decided to join the pharmaceutical industry in 1998 as a Clinical Research Associate (CRA) at Novartis Pharma GmbH. In 2000, I joined a medium-sized CRO in Darmstadt as a CRA where my focus was study management and writing study protocols and study reports. In 2002, I started with Merck¹ as a Clinical Document Manager dealing with document management systems and related tools. In 2005, I got the chance to combine both medical writing and document management expertise within the newly created position of Medical Writing Coordinator. The idea behind this position was to have one person to act as an interface with our preferred medical writing partners and to take care of the processing of documents as a whole. Somebody who keeps all the balls in the air. Currently we are 2 medical writing coordinators at Merck.

Can you give us some idea of the annual volume of work that your group deals with?

I oversee “only” our oncology projects: that means about 20 CSRs per year.

What sort of documents do you deal with most frequently, and do you supply your writers with templates, style guides and instructions?

Mainly study reports and study protocols as well as clinical summary and overview documents (CTD module 2.5 and 2.7). We expect all our internal and external writers to use our current set of templates and style guides, and we offer training. This prevents complex reworking scenarios when submissions to health authorities are near.

Who develops the templates?

Template creation is a combined effort of the respective discipline (e.g. clinical or non-clinical) and Regulatory Operations (REgOps). The discipline is responsible for the content of the template, and RegOps ensures that the latest requirements concerning formatting, styles and consistency over the different disciplines are met. The overall goal is to have submission-ready documents that fulfil all health authority requirements so that we can submit dossiers as quickly as possible without reworking.

What are the most complex documents and assignments to manage?

From my perspective, definitely the CSR. One of our latest CSRs had about 85,000 pages compiled from more than 300 single documents. Contributors to this CSR were spread all over the world—so this really was global medical writing, document management and publishing.

Do the clinical teams involve you when they are putting together clinical development plans, or are you not involved until the individual document-planning or writing stage?

Luckily, I am usually involved at a very early stage, but from time to time it happens that a request for medical writing support rears its head just before a deadline. We try to minimize such ‘accidents’ as far as possible, but have to be prepared for them to happen.

Do you have standard ‘numbers of days’ that you put into your plans for certain activities, such as preparation of study protocols, study reports of different complexities, review cycles, QC, and electronic publishing? If so, can you tell us what they are?

Yes, we have standard time slots, but we adapt these standards according to project priority and available resources to enable realistic planning. If a dossier submission is planned, everything is calculated to meet the submission timeline, and this may even mean that standard times are considerably revised. A rough plan is to have a submission-ready CSR approved 12 weeks after results are available.

You have in-house medical writers and work a lot with preferred partners. Does this make planning and scheduling more difficult?

We follow a mixed model with in-house writing and outsourcing to preferred partners. There’s no difference with respect to planning and scheduling. With our model, the external partners are members of the team just like internal colleagues. The ideal is to work with the same external medical writers on the same study teams over many years so we develop a close relationship, and we have been successful with this so far.

What are the greatest challenges when planning document preparation activities?

The greatest challenge is to come up with a realistic plan that considers the requirements of nearly all of the func-

¹ Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Merck is independent from Merck & Co. although we have common roots. In 1917 the then US subsidiary Merck & Co. was expropriated and has been an independent company ever since.

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tions involved. It is no good if your writing team completes their part on time and mandatory appendices for the CSR are still outstanding. So there is a lot of chasing up to do. The ability to deliver submission-ready documents means an increasing degree of technical expertise.

How have you tried to solve these?

On the one hand, each function and our and their requirements must be given equal consideration; on the other, you have to be able to be firm, and sometimes insistent, when the contributors have committed to the plan. Another inextricable step in writing dossiers these days is publishing, and we have learned to start preparing for publishing very early on in a project, even though the actually publishing is one of the last process steps. You have to avoid technical surprises at the end at all costs.

If you had three wishes that would make your work easier, what would they be?

- 1) Guaranteed user-friendly and robust tools (software, templates, document management).
- 2) It is a long time since the ICH E3 documentation was first issued, and I think it is high-time we had an update, because there are many improvements that could be made.
- 3) A Harry-Potter spell (Succedio Submissio!?) that would ensure that all our applications are automatically accepted (exclusive to Merck Serono, of course!).

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Making my day!

The following is an extract from an e-mail from Adam Jacobs that made my day:

“Right, I hope you're sitting down comfortably, because this is going to come as a bit of a shock. Here is my next article for *TWS*¹, submitted BEFORE the deadline.”

Elise Langdon-Neuner

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¹ 'Inside a research ethics committee' to be published in the December 2008 issue of *TWS*

Database of Uncertainties about the Effects of Treatments (DUETs)

This new database publishes uncertainties about treatments referring to reliable up-to-date systematic reviews of existing research evidence.

<http://www.duets.nhs.uk/>



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Editors are the 'gate-keepers' of the scientific literature, so maintaining integrity in all its forms is a vital aspect of what we do. This topic will be addressed in three plenary sessions and multiple parallel sessions. Submitted papers within this theme are also welcome. More practical workshops may be organised according to demand. There will also be a full social programme.

The deadline for abstract submission is 30 September 2008

For more information please go to
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